

REMARKS

Applicants file this Amendment in response to the Office Action mailed March 16, 2007.

The Office Action set an initial due date for response of June 18, 2007, and Applicants file this Amendment concurrently with a Request for Three-Month Extension of Time and associated fee.

In the Action, the Office considers and rejects all pending claims, 1-19. The present Amendment amends claim 7. The amendment of the claims finds support in the original claims and in the specification as filed, and the amendment adds no new matter.

Claim of Priority

Applicants note that the Examiner acknowledges the claim to priority, but the Office Action Summary indicates that “some” certified copies of the priority documents have been received. Applicants respectfully request the Examiner to clarify which priority documents the Patent Office has not received. If all of the priority document have been received, Applicants respectfully request the Examiner indicate accordingly in the next communication from the Office.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claim 7 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for recitation of a “sustained release formulation” yet for failing to indicate what type of sustained release formulation is claimed. In response, and without agreeing or acquiescing to the propriety of the rejection, Applicants amend claim 7 to replace “sustained release formulation” with “sustained release solid protein drug.” This amendment is similar to that suggested by the Examiner.

The Action also rejects claim 7 under 35 U.S.C. § 112, second paragraph, for the recitation of “*the solution*” and “*the solvent*” in lines 3 and 4 of the claim, alleging that there is a lack of antecedent basis for the terms. In response, and without agreeing or acquiescing to the propriety of the rejection, Applicants further amend claim 7 to make reference to “a solution” and “a solvent.”

Applicants submit that with the present amendment, the claims are even more definite and there should be no question about the metes and bounds. Applicants respectfully request withdrawal of this rejection of claim 7.

Claim Rejections – 35 U.S.C. § 102

The Office Action rejects claims 1-12 and 14-19 under 35 U.S.C. § 102(b) as allegedly anticipated by Scott et al. (WO 01/28524).

Applicants respectfully disagree with the rejection. The presently claimed invention is distinct from that disclosed in Scott et al. at least insofar as the presently claimed invention requires protein drug, sulfated polysaccharide, and hydrophobic material, such as fatty acid, palmitic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglyceride, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof (which are recited in claim 3), wherein the mixture of protein and sulfated polysaccharide is *encapsulated* with the hydrophobic material in the form of a hydrophobic matrix. As noted in the specification, this encapsulation to form a hydrophobic matrix keeps the *in vivo* release rate of the drug in a controlled and sustained manner for several days and weeks without high initial release.

In contrast, Scott et al. teach the use of a *water soluble polymer* to form microspheres.

Furthermore, while Scott et al. disclose microspheres comprising lipids and fatty acids,

Applicants note that Applicants' *matrix structures* which are composed of lipids and fatty acids are constitutionally different from *material-coated structures*, and this matter is well known to skilled persons in the art to which the present invention pertains. Thus, the hydrophobic material of the instant claims is structurally distinct from the water soluble polymers taught by Scott et al. Applicants also note that Scott et al. do not provide any working examples regarding the lipid or fatty acid coated-microsphere in the specification. Accordingly, Scott et al. fail to disclose or suggest the claimed sustained release solid formulation.

With regard to the process of preparing a sustained release solid formulation according to claims 7 and 12, the instant invention comprises a step of suspending the mixture in a solution containing hydrophobic materials, whereas Scott et al. teach making the microparticles by mixing the ingredients in an *aqueous solution*. Accordingly, Scott et al. fail to disclose or suggest the process to prepare a sustained release solid formulation as disclosed in the instant application.

For at least the foregoing reasons, Applicants submit that the claims are not anticipated by Scott et al. and respectfully request withdrawal of this rejection.

Claim Rejections - 35 U.S.C. § 103

The Office Action rejects claims 1-19 under 35 U.S.C. § 103 as allegedly obvious over Scott et al. (WO 01/28524). The Office alleges that many techniques are routinely used to make microparticles from synthetic and natural polymers, including spray drying, and that this is disclosed in the specification. The Action also asserts that spray drying was already well-known

and routine technique to dry particles. Therefore, the Action asserts, it would have been *prima facie* obvious to the skilled artisan that spray drying could be used to dry the microparticles disclosed in the Scott et al. document.

Applicants disagree. Scott et al. fail to disclose or suggest the claimed invention of the present application, as explained above. Thus, the cited art fails to provide all of the elements of Applicants' claimed invention. Additionally, Applicants respectfully note that there is nothing in the cited art that would lead to the particular structure of Applicants' claimed invention, and moreover, there is nothing in the cited art that would teach how to arrive at the particular structure of Applicants' claimed invention. Despite the Office's assertions to the contrary, there is nothing in Scott et al. that would have led to the choice of spray drying – or any other method that would have led to the presently claimed structure.

In view of the foregoing remarks, Applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness, and respectfully request its withdrawal.

Conclusion

In view of the foregoing remarks and amendments, Applicants respectfully submit that the claims are in condition for allowance. If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,
Hee-Yong LEE et al.


Bruce H. Bernstein
Reg. No. 29,027 42,920

September 14, 2007
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191